FDLI Medical Device Update

June 29, 1999

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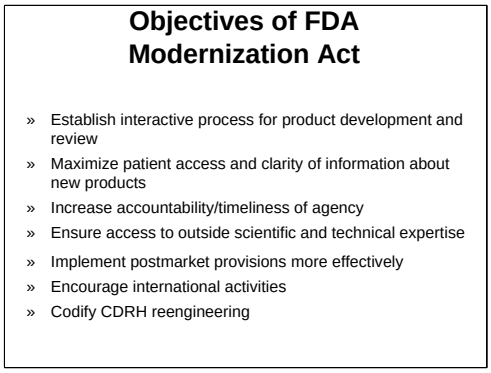
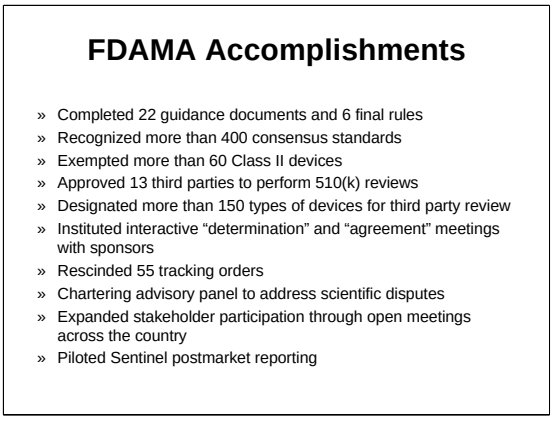
Let's Talk

- » FDAMA Implementation
- » Reengineering
- » Review Times
- » FDA Budget Impact on CDRH
- » Enhanced Science Base
- » Compliance Issues
- » International Issues
- » Y2K
- » User Fees

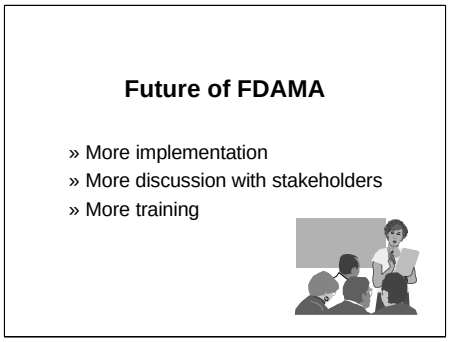
This is an overview of the subjects I plan to cover this morning. For the most part, they represent the issues you're planning committee identified: FDAMA, reengineering, review times, budget, enhanced science, compliance initiatives, international activities, and Y2K. I've taken the liberty of adding user fees because I could not resist the opportunity to share my own views on this issue with a captive audience.



- Dr. Henney has stated that implementation of the FDA modernization act of 1997 is her top priority. Needless to say, that is also a top priority of the center's.
- I think it is worth reiterating very briefly what FDAMA was intended to accomplish: first and foremost, with respect to medical device regulation, the statute was intended to encourage an interactive product development and review process; communication with industry is a primary directive of the new legislation.
- The new law also seeks to maximize patient access to promising therapies and products and to ensure that users and patients have information about products as early as possible.
- The law emphasizes the need for FDA to be timely and to be accountable in its decision-making.
- It encourages access and use of outside scientific and technical expertise.
- It encourages more effective and efficient use of postmarket controls such as tracking, postmarket surveillance studies, and injury reporting.
- And it directs the agency to engage in international activities that promote global harmonization.
- FDAMA also codifies many of the reengineering efforts that CDRH began before the legislation was passed -- e.g. expedited review of PMAs, Class I exemptions, and recognition of standards.



- This list illustrates the center's FDAMA implementation up until now.
- We were very anxious to avoid the kinds of delays in implementation that occurred following the Safe Medical Device Amendments of 1990.
- We succeeded in doing that (and I have to remind you that there were no additional funds appropriated for FDAMA) and I think most of you are probably very familiar with these achievements.
- We put out many guidance documents and final rules (more than many of you could digest).
- We recognized more than 400 consensus standards.
- We exempted more than 60 class II devices from premarket requirements.
- We put the third party review program into place on time, designated 13 third parties to do 510(k) reviews, and made more than 150 types of devices eligible for such review.
- We rescinded 55 tracking orders.
- We've begun chartering an outside panel to address scientific disputes.
- And we've piloted the Sentinel postmarket user reporting system.
- These were all necessary and important achievements and they reflect an enormous investment of center time and resources. But I think it is only fair to expect your question to be, "So what have you done for me lately?"



- So, let me try to anawer that.
- The future of FDAMA activities in the center will be more implementation, more discussion with stakeholders, and more training.

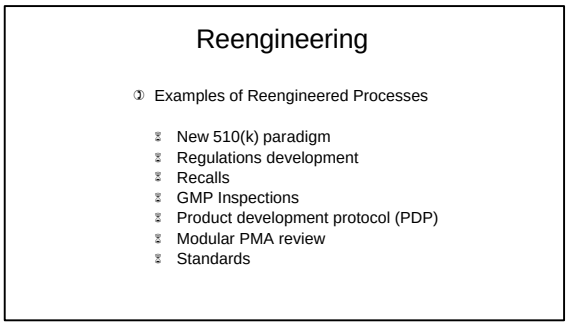
- FDAMA mandated many changes and many activities and it is taking time for the center culture to fully change and adapt. We recognize that there sometimes has been frustration with the pace of implementation at the staff level and we have heard your concerns that there are still reviewers and inspectors who are not comfortable with the collaboration and interaction that is so basic to FDAMA.

- We plan to address those concerns over the next year in a variety of ways.
    - We will be doing additional staff training and trying new formats and tools for that training: interactive computer program training, e.g., is being considered -- along with the possibility of simulations and demonstrations that will give people practice using the new process and approaches.

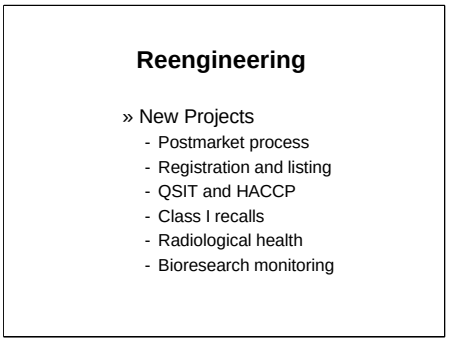
    - We also plan to review the guidances that we've already put out and see if there are additional refinements that make sense at this point.

    - Along with the rest of FDA, we will be conducting stakeholder meetings to hear from all our customers and, as the new Center Director, Dr. Feigal has personally made it a point to meet with many different groups and ask for input on a variety of issues, including FDAMA

    - The current projects that are consuming our energy are establishing ways to use the dispute resolution advisory panel required by FDAMA; preparing guidance that reviewers and industry will be able to use to interpret the "least burdensome" provision of the law; codifying the changes in the device tracking regulations; and preparing a report to Congress on the Sentinel reporting system, which I'll say a bit more about later.



- One of the most important aspects of FDAMA for us is that it codified a lot of what we were already doing in our reengineering efforts:
- As most of you remember, things were not going well in the early 90's. For a variety of reasons, we developed huge backlogs. Industry and Congress were both very critical of us. And morale was low.
- We dug ourselves out of these difficulties with the help of some workload management changes and, in 1994, some new resources of about $13 million, which went mostly to premarket review.
- For the last five years, we basically have had a flat budget but we've been getting a lot more work -- and implementation of FDAMA is just one reason.
- With more work and a flat budget, we needed to reexamine how we did our work and how to refocus resources from lower to higher risk products and activities. We embarked a couple years ago on some business-style reengineering.
- In the premarket notification area, we used a risk-based approach to target our resources. So we exempted most class I's and some II's from 510(k)s, and revamped the process to allow speedier handling of some changes and of applications where manufacturers declare conformance to standards -- the so-called new 510(k) paradigm.
- We improved project management for our regulations development activities, resulting in a better quality product that takes less time to complete.
- We delegated authority for lower-risk recalls to the districts, which had been making the recommendations anyway.
- We made a number of changes to GMP inspections. The field now notifies companies before routine inspections, which has resulted in more organized and efficient inspections. Companies can also make corrections on the spot to some deficiencies we find during the course of the inspection. This results in faster resolution of problems.
- And we revitalized an authority we already had but had not used, the product development protocol, where we and the manufacturer agree on the needed data and the product can go to market when the up-front agreement is fulfilled.
- We now have a process for accepting PMAs as a compilation of modules that together become a complete application. The process utilizes early meetings with industry to identify data needs and resolve issues. So far, we've received about 75 PMA shells. Four have been completed and 3 of them were done in under 180 days from start to finish.
- We have also recognized over 400 national and international standards, and have developed a standards database that can be accessed by all Center staff.

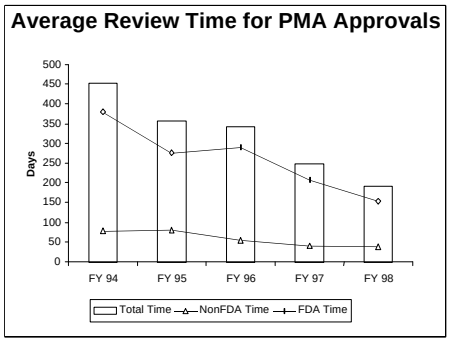


- Our reengineering efforts are continuing in several new areas. This list shows the new teams that are currently operating. The three I wanted to touch on here are postmarket process, registration and listing, and QSIT and HACCP.

- The postmarket process refers to what occurs to the product after it's on the market. We need to do a better job integrating our postmarket experience data, including adverse event data, with our premarket program, and we need to feed information back to manufacturers and users to improve the product and the ability of purchasers and patients to use it safely and effectively.

- We've held a number of meetings with industry and other stakeholders all across the country to discuss the possibility of manufacturers using the Internet to register and list electronically. This would streamline the process and reduce the burden on manufacturers and at the same time provide FDA with a more reliable database.

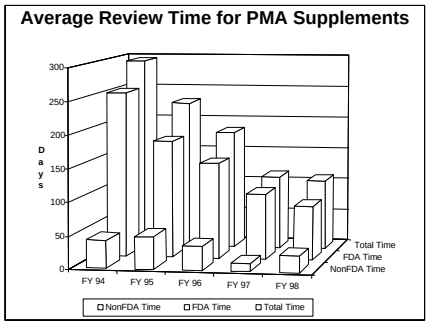
- QSIT is an acronym for Quality System Inspection Technique and HACCP is Hazard Analysis and Critical Control Points. I'll talk about them a little bit more later on. These are processes we're developing to change the nature of inspections to a quality systems approach. Our goals are to achieve shorter inspections that uncover the more important problems and result in more productive interactions with companies.



- One of the issues I was specifically asked to address was review times. This, of course, is always of special interest to our industry stakeholders.

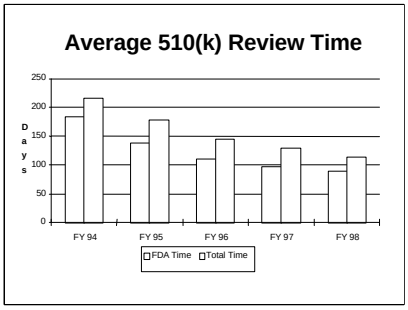
- The slides I am going to show you are all from the most recent ODE annual report and they tell the same success story in different ways. Review times have continued to decline over the past years, despite a shrinking workforce and increased complexity of the products being reviewed.

- Among other things, this slide shows that average FDA review times for PMAs have gone from about 375 days in 1994 to just about 190 days in 1998. That's a reduction of more than 50% in the time FDA reviewers spend on an application.



- The picture for supplements is similar.

- There has been a decrease in the time spent by FDA reviewers from 295 days to 107 days.

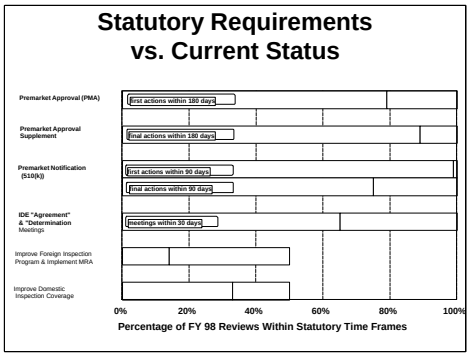


- And for 510(k)s, despite the fact that the 510(k)s left to review are the ones that are likely to be more complex than many of the ones we used to do that are now exempt, the time frames have continued to drop so that the average FDA review time in 1998 was 83 days.

Review Times Have Improved

» Direct infusion of money
» Redirected resources
» Reengineering (PMA-modules/PDP/510(k) paradigm)

- Review times have improved for a variety of reasons. I think the most important were: the direct infusion of money we received around 1994; the Center's conscious decision to redirect resources to premarket review; and the re-engineering initiatives that have produced the modular PMA program, the PDP approach, and the 510(k) paradigm.



- Another view of these review times, however, makes the picture more problematic. Despite the great gains we've made, we are not meeting the time frames of the act.

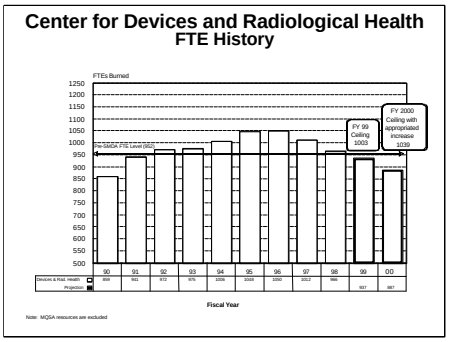
- This shows the percentage of FY'98 reviews that were handled within statutory time frames.

- Over 99% of 510(k) first actions were within 90 days, but the other premarket processes shown on the chart fell short of our prescribed time frames, as shown by red areas of the bars. And several of these measures are first actions, not final decisions. Both industry and the agency would like to get to final actions.

- The Center also did not meet its statutory obligations to do inspections of foreign and domestic firms.

- We will continue to look for efficiencies, but the reality is that we need resources if we are going to continue our improvement in meeting statutory obligations.

- At this time, given the likely budget outcomes, the Center is not projecting any performance improvement in review times over the next year and the reality is that we may not be able to maintain the gains we've already made.

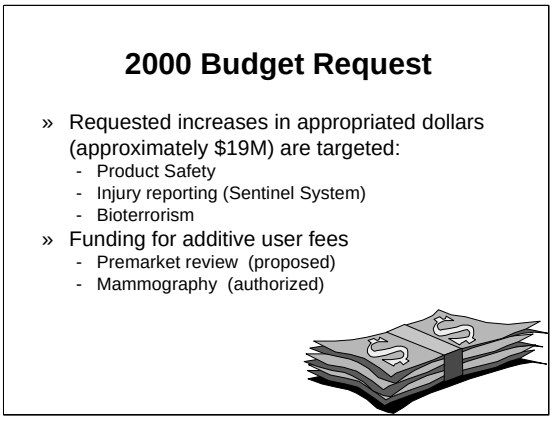


- CDRH's FTE history is one way to show how device resources have been steadily eroding for the last 4-5 years because the money we receive for the program has remained the same -- what we call "flat lined." That's a lot better than having a budget cut but it's critical for our stakeholders to realize that a flat budget does not really mean that our resources stay constant. A flat budget means we have the same amount of money to cover all the expenses that are built into the system such as inflation, cost of living, and salary increases. This translates into a real decrease of approximately 5% each year we "stay the same."

- In FY'99 we are at a resource crossroads. We have new responsibilities under FDAMA, increased interest in international activities, and the need to master emerging technologies. But the vast majority (almost 90%) of our declining purchasing power has to go to meet rising payroll costs for people already on board.

- We can't afford to hire up to our allotted FTE ceiling, because if we did, we'd have no money for operating expenses like rent, electricity, document control and data entry contracts.

- And because the percentage we have available over operating dollars is so low, there's not very much to spend on training, travel, and equipment for each employee.



- The President's FY2000 budget request for devices and radiological health is for a $27M increase.

- Almost $19M of that is for product safety, primarily for inspections, and most of that money would go straight to state contracts. This requested increase won't get us to inspections once every two years, but it would reverse the downward trend for class II and III devices.

- That requested increase includes $3.3M for injury reporting, most of which would go to the second phase of the pilot Sentinel reporting system.

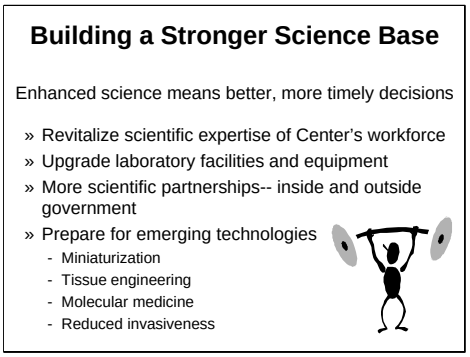
- The budget also includes a half million dollars for bioterrorism to hire experts for premarket review staff.

- $.4M is also included for current services in user fees for mammography.

- The latest House action on the Y2K budget cut $20M from FDA. The Senate hasn't taken any final action.

- The budget outlook is changing by the moment so I don't know where we'll end up. But the gap between what we need to do our job and the funding we have remains significant.

- When I talk about user fees in a little while I'll try to explain why I think that is one approach that has promise for future funding.



- Dr. Henney's second priority after FDAMA implementation is building the science base at FDA, but it is hard to imagine how that can happen without resources.

- Dr. Henney's vision is very clear: because FDA stands in judgment of the best science this country has to offer, this judgment should be made by the best, most well-prepared scientists, engineers, and clinicians.

- Some of you have heard me say before that enhancing the science base and the least burdensome provisions of FDAMA should really complement each other.

- People who are familiar with the newest technologies and risk assessment tools will ask the right questions, ask for the right amount of information, and ask only as often as necessary. A stronger science base will improve the soundness and timeliness of our decisions and get good products to market more quickly.

- Enhancing the science means many things:

- We need to revitalize the scientific expertise of our workforce, provide continuing education opportunities, and pay close attention to the infrastructure we have to support these people.

- This includes upgrading our laboratory facilities and equipment.

- It also includes continuing and expanding our partnerships with others. FDAMA calls for increased collaboration among FDA, NIH, and other science-based government agencies, but I think we need to expand that to industry and academia as well. We need to be able to participate in conferences, send our staff to training, collaborate with foreign counterparts, and learn about new materials and processes.

Challenge of New Technology Applications review or pending for:

» Artificial intelligence and visual recognition programs	19
» Data interpretation	132
» Software-driven monitoring devices with alarm function in critical care	222
» Software operated miniaturized devices	390
» Devices to support “minimally invasive” lesser invasive) procedures	58

- The challenge of new technology is one of the primary reasons we need to enhance the science base if FDA is not going to be a bottleneck for the cutting edge products that should get to market.

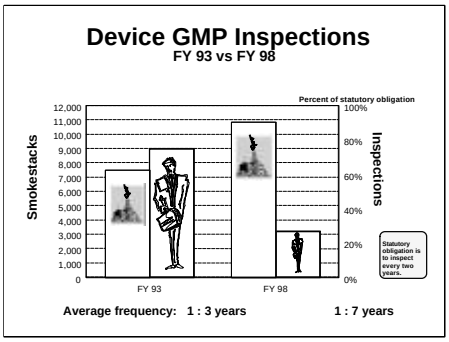
- At last count, there were about 800 device applications in house that depended on new or advanced technology. The slide lists some of the types of devices that have been reviewed or are pending that demonstrate the rapid advances the industry is making:

- Devices that use artificial intelligence and visual recognition programs, such as the latest automated Pap smear readers.

- Devices that interpret data or use software to monitor biologic parameters in critical care situations.

- And increasingly small devices that allow minimally invasive surgical procedures .

- I wanted to share one of the most recent applications with you.



- Enhancing the science base isn't something that applies only to the premarket activities of FDA.

- Providing training to our field staff, and in particular to the inspectors that visit facilities, is the kind of investment in science that should result in more efficient and more useful interactions between FDA and industry.

- Like reviewers, field Investigators who understand the materials and technology of the products being manufactured are more likely to ask the right questions, understand what they observe, and know what needs follow up.

- As I mentioned, there is a $27M increase request in the President's budget for CDRH. This slide of the "shrinking inspector" explains why most of this has been targeted for product safety, and, primarily, for inspections.

- The law requires us to do biennial inspections. In 1993 we were almost meeting that, at about 1 inspection per 3 years. But we're now down to 1 every 7 years on average.

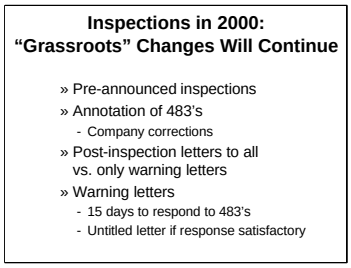
- A weak inspection program is bad for FDA, for consumers and for industry. When we don't inspect, there is a greater likelihood that there will be problems.

- In addition, if the inspection program is not credible and robust, confidence in the reengineering and FDAMA initiatives are bound to diminish because many of those new approaches rely on certification, standards, and third parties. If FDA does not inspect, no one can be sure these new approaches are working.

- As I mentioned earlier, the current request for 2000 won't get us to 100% of our statutory obligation but it will reverse the downward trend for class II's and III's. But we still would not be doing any routine class I inspections, which remains a problem because so many products are now exempt from premarket review of any kind.

- But just increasing the number of routine surveillance inspections isn't enough.

- We need to change how we do inspections: To make them more useful to manufacturers and consumers and to concentrate on the serious problems and not on the trivial ones.



- Our plans for inspections in the year 2000 are to continue implementing our reengineering initiative and to pilot some new ones.

- Reengineering our inspections started with the very successful grassroots program, in which industry worked with us to suggest needed changes.

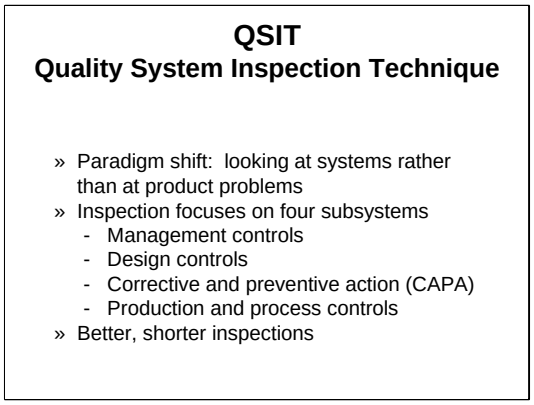
- As a result, a number of things have happened:
  - (1) We're now notifying companies before routine inspections. This has been very successful, and has resulted in more efficient inspections for us and less of a pop-quiz atmosphere for industry.
  - (2) We're allowing companies to make corrections to any deficiencies we find during the course of the inspection, on the spot, with those corrections recorded in the 483. This results in faster resolution of problems and companies don't get penalized for something they have already fixed.
  - (3) We're also sending close-out letters to all manufacturers at the end of the inspection -- Warning Letters if there's a serious problem, but more often a letter that says no additional follow-up is necessary, or that we noted some minor things and we'll look again next time.

- In March of this year, we began an 18-month pilot with warning letters. This program gives manufacturers 15 days to respond to the deficiencies noted in their 483, even if they might have warranted a warning letter. If the response is satisfactory, we'll send an untitled letter instead of a warning letter. We think that puts the incentive where it should be -- on rapid and effective correction.

- These changes are good but don't go far enough. We need to fundamentally change the nature of inspections -- what they look at and how they evaluate problems. They need to be shorter, more focused on the most important processes the company has, and more interactive.

- So … we are evaluating two types of processes, called by the acronyms, QSIT and HACCP.

- QSIT is Quality System Inspection Technique and HACCP is Hazard Analysis and Critical Control Points

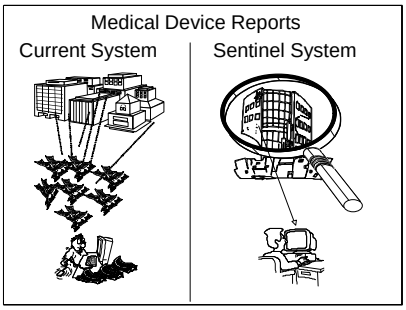


- QSIT is a real paradigm shift, where we look at systems rather than at product problems and industry has had a lot of input into the development of the QSIT approach.

- Inspection focuses on four major subsystems:
  - Management controls
  - Design controls
  - Corrective and preventive action (CAPA)
  - Production and process controls

- We've done a QSIT pilot of 42 inspections in 3 different districts (Denver, Los Angeles, Minneapolis) and our evaluation shows:
  - More important problems uncovered (primarily with management controls)
  - More positive interactions with the companies
  - Shorter inspections
  - In fact, historical data comparison shows comprehensive inspections went from 98 hours to 57 hours using QSIT, a 40% decrease.

- We'll be implementing this program more widely now that the pilot has proved so successful, but we will also be cautious and very receptive to feedback both from industry and FDA field operation.



- When you are receiving 70,000 - 80,000 medical device reports per year, it is time to rethink how you might process them more efficiently. Our system was becoming more and more paper intensive, and data entry was consuming more and more resources.

- So we began to allow summary reporting of device problems that we know a lot about. At present, 45 different manufacturers are participating in the program, and providing summary reports on 12 types of products. This reduces the number of individual reports we get. Last year, for instance, we received over 20,000 reports in summary form, and we hope to receive even more this year.

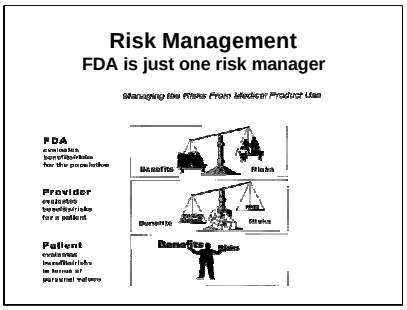
- We also pilot tested the “Sentinel” reporting system which would collect data electronically from a representative sample of hospitals and nursing homes rather than requiring universal reporting from every user facility.

- 24 facilities participated in the pilot, and we are encouraged by the results. Generally we got better quality and more frequent reports from our pilot facilities. We also got very positive feedback from the hospitals that participated. They were glad to get a quick and comprehensive responses to their reports instead of feeling they were being sent to some black hole.

- If we get funding in Y2000 to continue Sentinel, we will implement the next phase, which will expand the system to about 100 facilities.

- And if these efforts are successful, with continued funding we plan to implement Sentinel on a national level.

- Better postmarket reporting is critical to managing risk. Ultimately, a successful Sentinel program will mean a reduced reporting burden on most facilities and better information for FDA, manufacturers, and users.



- This is a good time to mention Dr. Henney's risk management initiative, because postmarket surveillance plays a very significant piece in that effort. Obviously, a vibrant and useful postmarket reporting system can identify and communicate risks associated with products that ordinarily have been tested on only a small and select population prior to marketing.

- The message the agency wants to convey is that effective risk management is the responsibility of all of us. FDA's role with respect to managing risk is primarily related to determining what can go on the market. Once a product is out there, however, product salesmen and health care practitioners play the major role in determining how often and under what circumstances the device is sold and prescribed. And then it is finally up to patients to decide, based on their personal situations and individual value systems, when a particular therapy is right for them.

- Managing the risk of medical products is also a global concern, and many of you know that the Global Harmonization Task Force, which is meeting this week in Bethesda (as we speak), has an entire study group devoted to postmarket surveillance.

- The GHTF is an example of the kind of activity FDAMA directs FDA to participate in in an effort to develop methods and approaches to harmonize regulatory requirements throughout the world.

- The Global Harmonization Task Force self assembled in 1992. The major players are the European Union, Canada, Japan, Australia, and the United States. Government and industry representatives of each country participate.

- The task force originally started out in a very informal way with no rules. Working groups were established for premarket requirements, postmarket requirements, especially adverse event reporting, and quality systems. FDA staff are influential in those groups and chair several of the committees.

- Those working groups now have documents they want received, revised and accepted by consensus, and it's clear that the task force needs to develop some more structure and procedures.

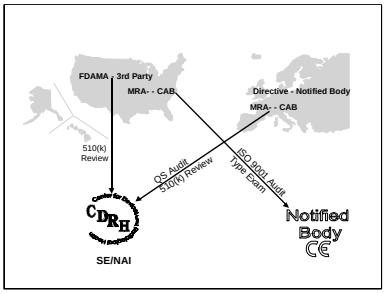
7th Meeting of the
Global Harmonization Task Force
Bethesda, MD
June 27 - July 1, 1999

http://www.ghtf.org

- Among other things, a primary objective of the current meeting is to establish procedures for the five principal governments to reach consensus on harmonization guidance documents. The hope is that the task force can agree to endorse a particular format or approach to device regulation and that all the member countries will then be persuaded to adopt that approach.

- International activities, like this one, are very expensive for FDA.

    - This year's meeting is right here in the Washington area, so participation is possible on a level we don't ordinarily enjoy. As you can imagine, when the meetings are held overseas, it is more difficult for us to be present and that sometimes sends the wrong message to our counterparts. They may think we don't take their activities seriously when the reality is simply that we don't have the bus fare to get there.



- Even more Center resources have been devoted to implementing the Mutual Recognition Agreement between the US and the European Union, which was signed 2 years ago.

- Among other things, the MRA covers pharmaceuticals and medical devices and its purpose is to facilitate transatlantic trade and reduce compliance costs.

- The MRA should become fully effective in 2001, after a 3-year confidence building transition. The centerpiece of the MRA is the idea of conformity assessment bodies -- CABs. These are third parties who will be qualified to act as regulatory surrogates to assess compliance with marketing and manufacturing requirements.

- Once the MRA is in place, EU CABS will be able to inspect companies in Europe that want to export medical devices to the US to see if those companies conform to FDA GMP requirements.

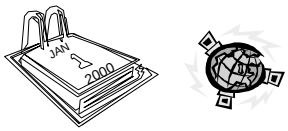
- US CABS will be able to inspect firms in the US that want to export to determine if their production conforms to EU quality systems requirements.

- In other words, each CAB will be checking to see if the firm complies with the manufacturing requirements of the country to which the product will be shipped.

- The other piece of the MRA allows the CABs of each party to do premarket reviews of products that are destined to be exported.

- A European CAB can conduct 510(k) evaluations based on FDA requirements for the same devices that are eligible for third party review in the Unites States. Similarly, a US CAB can conduct type-testing evaluations for certain devices that are being produced in the US for the EU market.

Year 2000
"PHRDs"



http://www.fda.gov/cdrh/yr2000/year2000.html

- Speaking of the year 2000, I, for one, am going to be very happy when January 1, comes and goes.

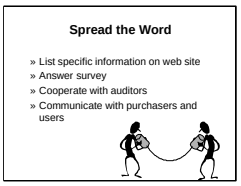
- Many people have expressed concern about what will happen to medical devices that are date dependent when the new millennium arrives.

- In response to those concerns and at the direction of the White House, OMB, HHS, and Congress, FDA has become something of a focal point for Y2K readiness. By this time, you all know we are running the government's Y2K web site on the status of biomedical equipment.

- We asked all manufacturers to list information about their equipment on the site -- whether their devices are date dependent; if so, do they have a problem-- if they have a problem, how can it be fixed? The FDA web site also provides links to manufacturers' individual web sites. Despite many letters from us, some companies have still not submitted information to the Website.

- Partly because the industry got off to a sluggish start, partly because we did not communicate our activities to a wide enough audience, and partly because there is a certain amount of hysteria out there about the new year, FDA has found itself in the position of having to do more and more to assure people that there are unlikely to be many serious problems with medical devices because of Y2K.

- FDA has recently identified and will list on the web, perhaps as soon as today, around 80 types of devices that are potentially high risk devices (we call them PHRDS) that could cause serious problems if they fail. Examples include: fetal cardiac monitors, emergency ventilators, and radiation therapy planning systems. The agency has identified about 650 manufacturers who make these types of devices.



- Beginning this summer, a contractor hired by FDA will begin to audit a sample of the manufacturers who make these PHRDS. The contractor will review the firms' records to see if they have instituted Y2K fixes, where necessary,and if those fixes were done in compliance with the quality system regulations.

- FDA is hopeful that the results of that first sample will provide sufficient verification that the device industry is doing what needs to be done.

- If it turns out that there are problems not being addressed properly, we expect the audit to expand.

- In addition to the concern about whether devices will work, there are concerns about possible supply shortages. Dr. Henney has just sent out a survey to all device manufacturers that requests information about the ability of these companies to rely on their supply and support systems. We hope this will help ensure uninterrupted production through the Y2K transition.

- I want to urge all of you to cooperate as much as possible in both the audit and survey activities so that we can provide the public and congress with confidence that medical devices will be available and continue to work in the year 2000.

- Companies that have addressed their Y2K problems need to publicize that as much as possible, get the information on our web site, and deal openly with healthcare facilities and other users who have questions about products they have purchased.

- Unless we work together to be as public as we can with information, things will just get worse as the clock ticks down to Y2K.

- And speaking of time running out, I'm going to use the last few minutes before questions to say a few words about user fees, beginning with the reasons so many people have hated them.

Top 10 Reasons Industry Has Hated Device User Fees

10. FDA already has enough appropriated dollars.
9. Fee revenues will simply replace appropriated revenues.
8. Existing resources can be reallocated to get devices out more quickly.
7. FDA review processes are inefficient.

Top 10 Reasons Industry Has Hated Device User Fees

6. Rigid reviewers create backlogs.
5. Review processes are fast enough.
4. Device manufacturers are very small businesses.
3. Fees could stifle innovative, start-up companies (and are un-American anyway).

Top 10 Reasons Industry Has Hated Device User Fees

2. _ _ _ _ _ _ _ _ _

1. _ _ _ _ _ _ _ _ _

(Add your personal favorites)

Why Consider User Fees Now?

- FDA has changed
  - streamlined and reengineered
- Industry has changed
  - robust and rapid growth
  - increasingly complex products
  - operating in global market
- Administration has changed its approach
  - proposing *additive* user fees for first time
- PDUFA has shown user fees can benefit industry, government, and consumers

Resources Are Shrinking

- » Flat line budgets have meant actual decrease in funds available for program.
- » CDRH FTEs have declined each of past three years — down 113 FTEs since FY 1996.
- » FDAMA added new responsibilities without funding.
- » International activities are costly.
- » Workload complexity is increasing.
- » Review timeframes are still too long (*e.g.*, PMAs – 12.4 months total elapsed time).
- » Administration's FY 2000 budget does not request additional premarket resources.

We've Gone About As Far As We Can Go

- Reengineering is bringing diminishing returns.
- FDAMA premarket provisions cannot be fully implemented without funding
- Product review program cannot meet all the demands placed on it; review times may slip
- CDRH cannot shift any more resources from other programs without jeopardizing public health
- The Administration proposal for additive fee legislation is opportunity for industry as well as FDA

Proposed Medical Device Fees

- » PMAs / PDPs — $40,000 each.
- » PMA supplements — $4,500 each.
- » Periodic PMA report — $1,000 each.
- » Establishment registration — $200 annually.
- □ *No fees for 510(k)s*

⇨ ***Would generate about $7 million***

Exceptions and Exemptions

- No *additional* fee for re-submissions.
- *No fee* for labeling changes that improve safety.
- Fees may be *waived or reduced* for —
  - Humanitarian devices.
  - When necessary to protect public health.
  - When fee would present significant barrier to innovation.
  - Small businesses with <20 employees and no prior PMA or 510(k).

Safeguards on the Use of Fees

- Legislation specifically requires all user fee revenues to be *additive.*
- Additive fee revenues *cannot be used to replace appropriated revenues.*
- Legislation *can guarantee stable funding* level because user fees cannot be assessed unless appropriations for the program remain at least constant.

What Can the Money Buy?

» Improved performance in FDA's medical device premarket review program.

- PMA first actions within 180 days --
  - FY99 -- 70%
  - With fees -- 85% in FY2000, 95% in FY2002
- Determination and IDE agreement meetings within 30 days --
  - FY99 -- 65%
  - With fees -- 95% in FY2000

» Investment in enhanced science at FDA

- increased training for reviewers on newest technologies and risk assessment tools
- increased standards development activities
- enhanced harmonization/international activities

Enhanced Science = Less Burdensome and More Timely Reviews Commensurate With Product Risk

- Scientific expertise helps reviewers understand type and amount of data necessary to establish safety and effectiveness
- Enhanced review program permits FDA to understand new technologies, regulate them in least burdensome manner.
- Staff armed with “cutting edge” science can make decisions more efficiently.

What's the Bottom Line?

- More rapid product development and approval
- Quicker access for patients; more rapid generation of income for companies
- Stable funding for device program at FDA
- More predictability about review process
- Other mutually beneficial deliverables

Think about it!